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| APPLICATION NO.            | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------|-------------|----------------------|---------------------|------------------|
| 10/656,653                 | 09/03/2003  | Daniel J. Cook       | 14/1454US           | 8300             |
| 22822                      | 7590        | 08/19/2008           | EXAMINER            |                  |
| LEWIS, RICE & FINGERSH, LC |             |                      | EREZO, DARWIN P     |                  |
| ATTN: BOX IP DEPT.         |             |                      |                     |                  |
| 500 NORTH BROADWAY         |             |                      | ART UNIT            | PAPER NUMBER     |
| SUITE 2000                 |             |                      |                     | 3773             |
| ST LOUIS, MO 63102         |             |                      |                     |                  |
|                            |             |                      | NOTIFICATION DATE   | DELIVERY MODE    |
|                            |             |                      | 08/19/2008          | ELECTRONIC       |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPDEPT@LEWISRICE.COM  
KADAMMAN@LEWISRICE.COM

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/656,653             | COOK, DANIEL J.     |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Darwin P. Erezo        | 3773                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 23 May 2008.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-18,20-43 and 45-48 is/are pending in the application.

4a) Of the above claim(s) 6,18,28 and 29 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-5,7-17,20-27,30-43 and 45-48 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/26/08</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____.                         |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of species III and V in the reply filed on 1/28/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. The examiner concurs with the applicant's definitions of Species II and III in page 3 of the remarks filed on 1/28/08.
3. Claims 6, 18, 28 and 29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected specie, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/28/08.

### ***Information Disclosure Statement***

4. The information disclosure statements (IDS) submitted on 3/26/08 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
6. Claims 1-5, 7-17, 20-27, 30-33, 35-39 and 45-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in

such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claims 1, 27, 30-33, 35, 45 and 46 have been amended to recite that the respiratory tube has a distal end passing through the (inflatable, hollow) peripheral portion of the positioning shield. However, there is no support for this limitation in the written disclosure. Instead, support is only provided for the distal end of the respiratory tube passing through the rear portion of the positioning shield (page 13, lines 4-5), wherein the rear portion of the positioning shield is located between the posterior base and the peripheral portion (page 12, lines 19-20). Note that the rear portion is a separate structure from the peripheral portion because it is disclosed to be formed between the posterior base and the peripheral portion.

Therefore, there is no support the distal end of the respiratory tube passing through the peripheral portion of the positioning shield (only for the rear portion) and that the amendment has introduce new matter into the disclosure.

Furthermore, Fig. 2 of the application clearly shows that the distal end of the respiratory tube will pass through the rear portion, which is located between the pliable, posterior base 42 and the hollow, inflatable peripheral portion 40.

#### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

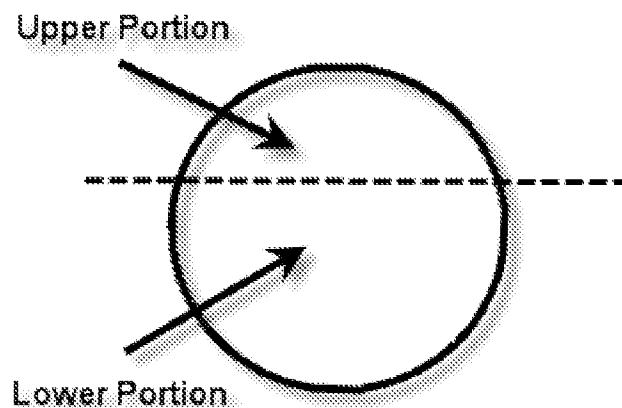
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 40 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,355,879 to Brain.

Brain discloses a laryngeal mask comprising having a means for alternative ventilation in the event the endotracheal tube is obstructed. The evacuation tube **51** is capable of providing alternate means of ventilation.

Brain further discloses a laryngeal mask having a distal lumen, wherein the distal lumen is a circular lumen, which can have an upper portion and a lower portion, and which is still smaller than the diameter of the tube adapter at the proximal end. The distal lumen can be divided into asymmetrical halves so that the upper portion can have a diameter that is different from the lower portion. See figure below.



9. Claims 34, 41-42 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,240,922 to Pagan.

(claim 34) Pagan teaches a laryngeal mask comprising horizontal runners **31-33** that is viewed as a means for elevating an epiglottis, which surrounds a portion of the perimeter of the lumen and does not obstruct the lumen. It is also noted that the Pagan reference qualify as a prior art because the structure of the horizontal rib is not present in any of the parent cases.

(claims 41-42) The horizontal runners is a means for inhibiting foreign matter.

***Response to Arguments***

10. Applicant's arguments with respect to claims 1-5, 7-17, 20-27, 30-33, 35-39 and 45-48 have been considered but are moot in view of the new ground(s) of rejection.

11. Applicant's arguments filed 5/23/08 have been fully considered but they are not persuasive.

The applicant's argument that Brain fails to teach the limitations of claim 43 is not persuasive because the claim does not specifically recite a "keyhole". Instead, the claim merely recites a lumen having an upper portion and a lower portion. As seen above, a circular lumen can be sectioned off to an upper portion and a lower portion, wherein the upper portion has a diameter that is different from the lower portion.

It is also noted that the applicant has not provided an argument for claim 40. Thus, the rejection stands unchanged.

With regards to the arguments that the Pagan reference does not constitute as prior art, this is not persuasive because the original parent application 08/843,631 (5,937,860) does not provide support for the claimed limitations. Independent claim 34 recites the limitation of “a means for elevating an epiglottis, the means surrounding at least a portion of the perimeter of the lumen formed by the distal end of the respiratory tube”. This structure surrounding a portion of the perimeter of the lumen of the distal end is not supported in the parent case. Claims 41 and 42 recite the limitation of “means for inhibiting foreign matter from entering the epiglottis, wherein the means for inhibiting comprises at least one raised horizontal runner”. This limitation is also not supported in the parent case. The parent case teaches two semi-rigid raised runners 44 (not horizontal) that guide the placement of the inflatable positioning shield. The runners are not used to inhibit foreign matter from entering the epiglottis. Therefore, the earliest priority date for the limitations in the claims are the filing of the instant continuation-in-part application, which is 09/03/2003, and that the Pagan reference is available as a proper prior art.

***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezo whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Darwin P. Erez/  
Primary Examiner, Art Unit 3773